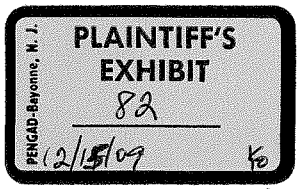
EXHIBIT 82



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UNITED STATES OF AMERICA,	)	
	)	
Plaintiff,	)	
	)	Hon.
v.	)	
	)	Civil Action No.
ACTAVIS TOTOWA, LLC,	)	
ACTAVIS, INC.,	)	
corporations, and	)	
SIGURDUR OLI OLAFSSON,	)	
DOUGLAS BOOTHE,	)	
individuals,	)	
	)	
Defendants.	)	

COMPLAINT FOR PERMANENT INJUNCTION

The United States of America, by and through its undersigned attorneys, respectfully states as follows:

INTRODUCTION

1. This statutory injunction proceeding is brought under the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 332(a), to permanently enjoin the defendants, Actavis Totowa, LLC (Actavis Totowa), Actavis, Inc., Sigurdur Oli Olafsson, and Douglas Boothe (collectively referred to hereinafter as "Defendants") from: (a) violating 21 U.S.C. § 331(a) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce drugs that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B); (b) violating 21 U.S.C. § 331(k) by causing drugs that Defendants hold for sale after shipment of one or more of their components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B); (c) violating 21 U.S.C. § 331(a) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce drugs that are misbranded within the meaning of 21 U.S.C. § 352(f)(1); (d) violating 21 U.S.C. § 331(k) by causing drugs that Defendants hold for sale after shipment of one or more of their components in interstate commerce to become misbranded within the meaning of 21 U.S.C. § 352(f)(1); and (e) violating 21 U.S.C. § 331(d) by introducing or delivering, or causing to be

introduced or delivered, into interstate commerce new drugs that are neither approved pursuant to 21 U.S.C. § 355(a), nor exempt from approval pursuant to 21 U.S.C. § 355(i).

JURISDICTION

2. This Court has jurisdiction over the subject matter and over all parties in this action pursuant to 21 U.S.C. § 332(a) and 28 U.S.C. §§ 1331, 1337, and 1345.

VENUE

3. Venue in this district is proper under 28 U.S.C. §§ 1391(b) and (c).

DEFENDANTS

4. Actavis Totowa is a limited liability company that manufactures, processes, packs, labels, holds, and distributes drugs from three sites in New Jersey, all within the jurisdiction of this Court: 990 Riverview Drive, Totowa, NJ (Riverview Drive facility); 4 Taft Road, Totowa, NJ (Taft Road facility); and 101 East Main Street, Little Falls, NJ (Little Falls facility). Most of the firm's manufacturing operations and receipt of raw materials occurs at the Little Falls facility. At the Taft Road facility, the firm conducts research and development, receives components, and labels, packages, and distributes finished products. At the firm's new Riverview Drive facility, Actavis Totowa recently started laboratory

testing and some other drug manufacturing activities. Actavis Totowa is a wholly-owned subsidiary of Actavis, Inc.

5. Actavis, Inc. is the United States manufacturing and marketing division of Actavis Group hf, an international generic pharmaceutical company located in Reykjavik, Iceland, and the direct parent of Actavis Totowa. Actavis, Inc. is located in Morristown, New Jersey, within the jurisdiction of this Court. Actavis, Inc. exercises senior management oversight of and control over, among other things, Actavis Totowa's drug manufacturing operations.

6. Sigurdur Oli Olafsson became the Managing Director of Actavis, Inc. in 2003 and held that position for a period of time. Earlier this year, he returned to the United States to act as the interim Chief Executive Officer (CEO) of Actavis, Inc. Mr. Olafsson helped manage Actavis Totowa's response to the Food and Drug Administration (FDA's) findings during its most recent inspection of Actavis Totowa's Riverview Drive facility in 2008, including meeting with FDA to discuss the agency's findings and directly communicating his company's responses to FDA. Mr. Olafsson is currently the Executive Chairman of Actavis, Inc.

7. In 2005, Douglas Boothe became the Vice President and Corporate Operating Officer for Actavis, Inc. After that, he was Executive Vice President for U.S. Commercial and Administration. In August 2008, Mr. Boothe assumed the

position of President and CEO of Actavis Totowa. He is responsible for all activities at the Actavis Totowa facilities, including, but not limited to, their manufacturing and testing of drugs.

8. Defendants have been, and are now engaged in manufacturing, processing, packing, labeling, holding, and distributing drugs within the meaning of 21 U.S.C. § 321(g).

9. Defendants' drugs are "new drugs" within the meaning of 21 U.S.C. § 321(p)(1), because they are not generally recognized among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in their labeling.

10. Defendants regularly manufacture drugs using components that they receive in interstate commerce and introduce finished drugs into interstate commerce for shipment outside of New Jersey.

ADULTERATED DRUGS

11. FDA's five inspections of Actavis Totowa's facilities over the last three years have revealed numerous and recurring violations of the current Good Manufacturing Practice (CGMP) requirements for drugs in violation of the FDCA. FDA inspected Actavis Totowa four times in 2006 and 2007: three times at the

firm's Little Falls facility and one time at the firm's Taft Road facility. FDA issued Warning Letters to Actavis Totowa in 2006 and 2007. Most recently, from March 18 through May 20, 2008, FDA inspected Actavis Totowa's new Riverview Drive facility, and again found numerous and significant violations of the CGMP requirements.

12. FDA's inspections establish that the drugs being manufactured and distributed by Defendants are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B), in that the methods used in, or the facilities or controls used for, their manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with the CGMP requirements for drugs.

13. Compliance with the CGMP requirements assures that drugs meet the requirements of the FDCA as to safety and have the identity and strength and meet the quality and purity characteristics that they purport or are represented to possess. Drugs not manufactured, processed, packed, or held in conformance with CGMP requirements are deemed adulterated as a matter of law, without any showing of actual defect. Regulations implementing the CGMP provisions are set forth at 21 C.F.R. Parts 210 and 211.

14. Defendants have violated the FDCA, 21 U.S.C. § 331(a), by introducing and delivering for introduction into interstate commerce articles of

drug, as defined by 21 U.S.C. § 321(g)(1), that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B), as set forth below.

15. Defendants have violated the FDCA, 21 U.S.C. § 331(k), by causing the adulteration, within the meaning of 21 U.S.C. § 351(a)(2)(B), of articles of drug, as defined by 21 U.S.C. § 321(g)(1), while such articles are held for sale after shipment of one or more of their components in interstate commerce.

16. FDA's inspection of Actavis Totowa's Little Falls facility from January 10 to February 8, 2006, revealed that the firm failed to comply with CGMP requirements in several respects, including, for example, that: (1) it failed to investigate unexplained out-of-specification testing results for drugs, 21 C.F.R. § 211.192; (2) it failed to establish control procedures to validate the performance of manufacturing processes, 21 C.F.R. § 211.110(a); and (3) its quality control unit failed to initiate an investigation when there were multiple complaints for the same lot of product or confirmed contamination complaints, 21 C.F.R. § 211.198(a). At the close of the inspection, on February 8, 2006, FDA provided Actavis Totowa with an FDA Form-483, List of Inspectional Observations (Form-483), setting forth the agency's inspectional observations, and the investigators discussed the findings with the firm's management.

17. From July 10 to August 10, 2006, FDA conducted another inspection of Actavis Totowa's Little Falls facility, and observed numerous CGMP deficiencies that were the same or similar to the observations from the previous inspection, including, but not limited to, that the firm: (1) kept incomplete laboratory records of all testing data, 21 C.F.R. § 211.194(a)(4), and failed to verify the suitability of all testing methods used under actual conditions of use, 21 C.F.R. § 211.194(a)(2); (2) failed to investigate unexplained out-of-specification testing results for drugs, 21 C.F.R. § 211.192; (3) failed to follow its written stability testing program, 21 C.F.R. § 211.166(a); (4) failed to record and justify deviations from its written production and process control procedures, 21 C.F.R. § 211.100(b); and (5) failed to examine and test samples to ensure that in-process materials conform to their specifications, 21 C.F.R. § 211.110(b). The inspection also revealed that the firm's quality control unit did not follow its written procedures, 21 C.F.R. § 211.22(d), and failed to ensure that all data was reviewed and laboratory deviations were fully investigated and resolved prior to the release of drugs into commercial distribution, 21 C.F.R. § 211.22(a). At the close of the inspection, on August 10, 2006, FDA provided Actavis Totowa a Form-483 setting forth the agency's inspectional observations, and the investigators discussed the findings with the firm's management.

18. From September 18 through October 11, 2006, FDA inspected Actavis Totowa's Taft Road facility and found deviations from the CGMP requirements that were the same or similar to those that were previously observed and, as explained below, were observed again later at Actavis Totowa's facilities, including that the firm: (1) deviated, without written justification, from its own written specifications, test procedures, and laboratory mechanisms, 21 C.F.R. § 211.160(a); (2) had not established the accuracy, specificity, and reproducibility of the test methods that it employed, 21 C.F.R. § 211.165(e); and (3) failed to verify the suitability of all testing methods used under actual conditions of use, 21 C.F.R. § 211.194(a)(2). At the close of this inspection, FDA gave Actavis Totowa a Form-483 setting forth its observations, and the investigators discussed the findings with the firm's management.

19. In February 2007, FDA sent Actavis Totowa a Warning Letter, citing the CGMP violations found during the July/August 2006 Little Falls facility inspection. The Warning Letter listed many of the significant CGMP violations observed at the firm, and warned the firm that failure to correct all of the violations could result in regulatory action, including injunction.

20. FDA inspected the Little Falls facility again from September 5 through 28, 2007. During this inspection, FDA observed that the firm's significant

CGMP violations continued, including that the firm failed to follow its written stability testing program, 21 C.F.R. § 211.166(a), and failed to follow its written production and process control procedures, 21 C.F.R. § 211.100(b).

21. From March 18 to May 20, 2008, FDA inspected Actavis Totowa's Riverview Drive facility. Throughout the inspection, the FDA investigators advised Defendants of the numerous and significant deviations from the CGMP requirements that the investigators observed so the firm could take responsive actions to protect the public health. During this inspection, FDA observed significant CGMP violations, which were the same or similar to the deviations observed by FDA during its previous inspections of Actavis Totowa facilities in 2006 and 2007. These deviations included, but were not limited to, the firm's failure to: (1) have adequate written procedures for its quality control unit, and to have its quality control unit document and investigate the failure of a batch of drugs to meet specifications, 21 C.F.R. § 211.22(a) and (d); (2) reject drug products failing to meet established standards or specifications and any other relevant quality control criteria, 21 C.F.R. § 211.165(f); (3) investigate unexplained out-of-specification testing results for drugs, 21 C.F.R. § 211.192; (4) have laboratory controls sufficient to ensure that components, in-process materials, and finished drug products have the appropriate standards of identity, strength,

quality, and purity and conform to their written specifications, 21 C.F.R. § 211.160(b); and (5) record and justify deviations from their written production and process control procedures, 21 C.F.R. § 211.100(b). At the close of the inspection, on May 20, 2008, the FDA investigators provided Defendants with a Form-483 setting forth the inspectional observations, and the investigators discussed the findings with the firm's management.

UNAPPROVED NEW DRUGS AND MISBRANDED DRUGS

22. FDA's inspection of Actavis Totowa's Little Falls facility from January 10 to February 8, 2006, discussed in paragraph 16 above, also revealed that certain of the drugs manufactured and distributed by Actavis Totowa lacked approved new drug applications (NDAs) or approved abbreviated new drug applications (ANDAs) as required by 21 U.S.C. § 355, and were not exempt under 21 U.S.C. § 355(i) from the FDCA's pre-market approval requirements. As a result, these drugs were unapproved new drugs within the meaning of 21 U.S.C. § 355(a).

23. On August 15, 2006, FDA sent Actavis Totowa a Warning Letter related to the January 10 to February 8, 2006 Little Falls inspection, warning that, among other things, the firm's manufacture and distribution of numerous unapproved prescription drug products violated the FDCA's drug approval

requirements. The Warning Letter informed Actavis Totowa that it should take prompt action to correct all deficiencies observed during the January/February 2006 inspection, or FDA may take regulatory action, including seeking an injunction. FDA copied defendant Sigurdur Olafsson, then President of Actavis, Inc., on this Warning Letter.

24. FDA's March 18 to May 20, 2008 Riverview Drive inspection, discussed in paragraph 22 above, revealed that Defendants continued to manufacture and distribute unapproved new drugs.

25. Defendants violated 21 U.S.C. § 331(d) by introducing or causing to be introduced into interstate commerce unapproved new drugs.

26. Defendants' unapproved new drugs are also misbranded drugs, because they lack scientific evidence to demonstrate that they are safe and effective as indicated in their directions for use. Such drugs do not bear adequate directions for use as required by 21 U.S.C. § 352(f)(1), and they are not exempt from this requirement pursuant to 21 C.F.R. §§ 201.115 or 201.100. A prescription new drug is exempt from the adequate directions for use requirement only if it bears the precise labeling approved in its NDA. Thus, any prescription new drug that lacks an approved NDA cannot satisfy this condition for exemption from the adequate

directions for use requirement and, therefore, is misbranded until such time as its NDA is approved by FDA.

27. Defendants violated the FDCA, 21 U.S.C. § 331(a), by introducing and delivering for introduction into interstate commerce articles of drug, as defined by 21 U.S.C. § 321(g)(1), that are misbranded within the meaning of 21 U.S.C. § 352(f)(1), as set forth above.

28. Defendants violated the FDCA, 21 U.S.C. § 331(k), by causing the misbranding, within the meaning of 21 U.S.C. § 352(f)(1), of articles of drug, as defined by 21 U.S.C. § 321(g)(1), while such articles are held for sale after shipment of one or more of their components in interstate commerce.

PRIOR WARNINGS TO DEFENDANTS

29. As previously alleged, at the close of all of the Actavis Totowa inspections discussed above, FDA investigators provided a Form-483, listing the inspectional observations, to the company and its management and discussed their findings with the company. At the close of the 2008 Riverview Drive inspection and the 2007 Little Falls inspection, FDA investigators discussed the Form-483 with Defendants.

30. Also as previously alleged, FDA issued Warning Letters to Actavis Totowa on August 15, 2006, citing the firm for, among other things, its

manufacture and distribution of numerous unapproved new drugs, and on February 1, 2007, citing the firm for its deviations from the CGMP requirements. The letters explain that Actavis Totowa's failure to correct the violations could lead to regulatory action, including an injunction.

31. Further, FDA participated in a meeting with Defendants Sigurdur Oli Olafsson, among others, on April 23, 2008, during which FDA discussed Defendants' non-compliance with CGMP.

RELIEF REQUESTED

32. The United States is informed and believes that, unless restrained by this Court, Defendants will continue to violate the FDCA, 21 U.S.C. §§ 331(a), (d), and (k) in the manner herein alleged.

33. The United States requests that Defendants Actavis Totowa, LLC, Actavis, Inc., Sigurdur Oli Olafsson, and Douglas Boothe, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them, be enjoined from manufacturing, processing, packing, labeling, holding, or distributing articles of drug, unless and until Defendants' methods, facilities, and controls used to manufacture, process, pack, label, hold, and distribute articles of

drug are established, operated, and administered in conformity with the CGMP requirements and the FDCA, in a manner acceptable to FDA.

34. The United States requests that Defendants Actavis Totowa, LLC, Actavis, Inc., Sigurdur Oli Olafsson, and Douglas Boothe, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with them be permanently restrained and enjoined under 21 U.S.C.
§ 332(a) from directly or indirectly doing or causing to be done any of the following acts:

A. Violating 21 U.S.C. § 331(a) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce drugs that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B); and

B. Violating 21 U.S.C. § 331(k) by causing drugs that Defendants hold for sale after shipment of one or more of their components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B);

C. Violating 21 U.S.C. § 331(a) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce drugs that are misbranded within the meaning of § 352(f)(1);

D. Violating 21 U.S.C. § 331(k) by causing drugs that Defendants hold for sale after shipment of one or more of their components in interstate commerce to become misbranded within the meaning of 21 U.S.C. § 352(f)(1); and

E. Violating 21 U.S.C. § 331(d) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce new drugs that are neither approved pursuant to 21 U.S.C. § 355(a), nor exempt from approval pursuant to 21 U.S.C. § 355(i).

35. The United States requests that FDA be authorized pursuant to this injunction to inspect Defendants' places of business and all records relating to the receipt, manufacture, processing, packing, labeling, holding, and distribution of any drug to ensure continuing compliance with the terms of the injunction, with the costs of such inspections to be borne by Defendants at the rates prevailing at the time the inspections are accomplished; and

36. The United States requests that this Court award it costs and other such equitable relief as this Court deems just and proper.

Respectfully submitted,

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